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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,377	02/08/2002	Gert Hobom	100727-14 /Kreisler 1094-	5110

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KURT BRISCOE
NORRIS, MCLAUGHLIN & MARCUS, P.A.
220 EAST 42ND STREET, 30TH FLOOR
NEW YORK, NY 10017

EXAMINER

LI, BAO Q

ART UNIT PAPER NUMBER

1648

DATE MAILED: 09/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/073,377

Applicant(s)

HOBOM ET AL.

Examiner

Bao Qun Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 1-52 are pending.

Election/Restrictions

Upon considering the claimed inventions, a restriction is required under 35 U.S.C. 121:

- I. Claims 1-11 and 30, drawn to a human influenza virus comprising an RNA-sequence encoding a modified RNA-polymerase, classified in class 424, subclass 209.1.
- II. Claims 12-26, drawn to a modified influenza virus, which is suitable for high yielding expression of one or more foreign recombinant or altered viral protein, classified in class 435, subclass 320.1.
- III. Claim 27, 31 and 48-49, drawn to a porcine influenza virus, classified in class 424, subclass 93.2.
- IV. Claims 28-29, drawn to a method of making a recombinant influenza virus, classified in class 435, subclass 91.1.
- V. Claims, 32-33, 37-41, drawn to a method for gene therapy, classified in class 424, subclass 93.1.
- VI. Claims 34-36, drawn to a method for producing a recombinant protein in cell culture or fertilized chicken egg by using an influenza virus, classified in class 435, subclass 69.1.
- VII. Claims 42-43, drawn to a vaccine, classified in class 424, subclass 199.1.
- VIII. Claims 44-45, drawn to a transduced cells and a vaccine comprising a transduced cells, classified in class 435, subclass 325.
- IX. Claims 46-47, drawn to a method for identifying a polynucleotide sequence, classified 435, subclass 5.
- X. Claim 50, drawn to a method of transferring a gene into a cell by using a non-human influenza virus, Classified in class 435, subclass 440,
- XI. Claim 51-52, drawn to a method for an ex vivo or an in vivo immunotherapy for a patient by using a dendritic cells infected with a modified influenza virus classified in class 424, subclass 9.31.

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If Group any one of the groups I to XI is selected, a further restriction/election on following RNA is required under 35 U.S.C. 121:

- 1). SEQ ID NO: 27,
- 2). SEQ ID NO: 29,
- 3). SEQ ID NO: 31,
- 4). SEQ ID NO: 33,
- 5). SEQ ID NO: 35,
- 6). SEQ ID NO: 37,
- 7). SEQ ID NO: 39,
- 8). SEQ ID NO: 41,
- 9). SEQ ID NO: 43,
- 10). SEQ ID NO: 45,
- 11). SEQ ID NO: 47.

If any one Groups from I to XI is selected, a further restriction/election on following DNA is required under 35 U.S.C. 121:

- i). SEQ ID NO: 26,
- ii). SEQ ID NO: 28,
- iii). SEQ ID NO: 30,
- iv). SEQ ID NO: 32,
- v). SEQ ID NO: 34,
- vi). SEQ ID NO: 36,
- vii). SEQ ID NO: 38,
- viii). SEQ ID NO: 40,
- ix). SEQ ID NO: 42,
- x). SEQ ID NO: 44,
- xi). SEQ ID NO: 46.

If any one of Groups from I to XI is selected, a further restriction/election on following 3' terminal nucleotide sequence is required under 35 U.S.C. 121:

- A). SEQ ID NO: 5,
- B). SEQ ID NO: 4.

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The inventions are distinct, each from the other because of the following reasons:

1. Inventions of groups 10) to 11) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of groups 1) to 11) have different structures and functions, which require different searches and have different patentable weights, e.g. the sequence of group 1) is SEQ ID NO: 27, whereas the sequence of Group 2) is SEQ ID NO: 29.
2. Inventions of groups i) to xi) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of groups i) to xi) have different structures and functions, which require different searches and have different patentable weights, e.g. the Sequence of Group i) is SEQ ID NO: 26, whereas the sequence of Group ii) is SEQ ID NO: 28.
3. Inventions of groups A) to B) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of groups A) to B) have different structures and functions, which require different searches and have different patentable weights, e.g. the Sequence of Group A) is SEQ ID NO: 5, whereas the sequence of Group B) is SEQ ID NO: 4.
4. Inventions of groups I-III and VII-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of groups I-III and VII-VIII have different structures and functions, which require different searches and have different patentable weights, e.g. the recombinant virus of Group I is a human influenza virus, whereas the recombinant virus in Group III is a non-avian, non-human influenza virus, porcine influenza virus.
5. Inventions of groups IV-VI to IX-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of groups IV-VI) to IX-XI) have different structures and

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functions, which require different searches and have different patentable weights, e.g. the method of Group IV is for making a recombinant influenza virus, whereas the method of Group XI is an ex vivo or an in vivo immunotherapy for a patient by using a dendritic cells infected with a modified influenza virus.

6. Inventions Groups I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process, such as to modified the non-structural protein NS1 of an influenza virus, rather than modified the RNA-polymerase.

7. Inventions of Groups II and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the product as claimed can be practiced with another materially different product, e.g. by using a adenovirus vector rather than influenza viral vector.

8. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group XI, restriction for examination purposes as indicated is proper.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

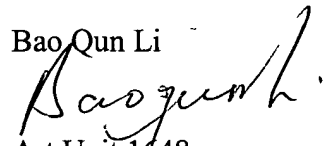
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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li



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September 20, 2003